REMARKS

Reconsideration of the above-identified application in view of the above amendments and following remarks is respectfully requested.

Claims 17 and 26 have been amended to include the phrase, "and an assay diluent which comprises a large polycation". Support for this phrase can be found on page 8, lines 10-11. Thereupon, Applicant submits that these amendments do not involve any new matter.

Claim 3 has been amended to correct a typographical error, namely, the underlining of "polyornithine."

Claim Rejections - 35 U.S.C. Section 112

Claims 17 and 26 are rejected under 35 U.S.C. Section 112, second paragraph as being indefinite. More specifically, the Examiner states that each of these claims is missing a critical step. Applicants have amended each of these claims to include "an assay diluent comprising a large polycation". The specification describes an assay diluent comprising a large polycation can be used in the claimed method to decrease the interferences in the serum or plasma sample.

Therefore, in view of the aforementioned amendments, Applicants submit that this rejection is now moot and should be withdrawn.

Claim Rejections - 35 U.S.C. Section 102

Claims 1-13 are rejected under 35 U.S.C. Section 102(e) as being anticipated by Petry et al. (U.S. Patent No. 6,406,858). Applicants respectfully traverse this rejection.

The Examiner states that Petry et al. teach an improvement to the method of determining the concentration of an analyte in body fluid. This method uses at least two immunoreactants that specifically bind with separate epitopes of the analyte. The improvement in this method relates to adding what is called a "scavenger conjugate" during the assay. This "scavenger conjugate" comprises an enzyme and a water-soluble protein or a non-proteinaceous natural, synthetic or semi-synthetic polymer or oligomer. Examples of non-proteinaceous natural, synthetic or semi-synthetic polymers or oligomers that can be used are polylysine, polyasparagine and dextranes (see column 4, lines 16-17). The "scavenger conjugate" is added to the assay in order to "reduce the interaction of the unknown interferents" (column 2, lines 49-50).

Applicants submit that there is nothing in Petry et al. that teaches or suggests to one of ordinary skill in the art that a large polycation that is not conjugated to an enzyme can be used in a specific-binding assay to decrease the interference caused by non-optimal serum or plasma sample preparation techniques, including, but not limited to, inadequate centrifugation, incomplete clotting time, exposure to thermal stresses, etc. In fact, Applicants submit that Petry et al. actually teach away from the present invention. More specifically, in column 2, lines 57-65, Petry et al. state the following:

> "While a polymer made up by the readout enzyme only shows a limited amount of effectiveness, polymers made from only the second component of an effective scavenger conjugate (e.g. Bovine Serum Albumin (BSA), Bovine Gamma Globulin (BGG) or Keyhold Limpet Hemocyanin (KLH) or of copolymers from the second component of the scavenger with fragments of itself as described in U.S. Pat. No. 4,914,040 are completely ineffective." (Emphasis added)

Clearly, Petry et al. teach that it is only the combination of an enzyme and the water-soluble protein or a non-proteinaceous natural, synthetic or semi-synthetic polymer or oligomer that can be used in assays to "reduce the interaction of the unknown interferents". Therefore, because each and every element of the claimed invention is not disclosed by Petry et al., Applicants submit that this rejection should be withdrawn.

Claim Rejections - 35 U.S.C. Section 103(a)

Claims 15 and 16 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over Petry et al. The Examiner states that Petry et al. fail to teach detecting free prostrate specific antigen. However, the Examiner argues that it would have been obvious to one of ordinary skill in the art to detect free prostate specific antigen since Petry et al.'s method can be used to detect prostate specific antigen. Applicants respectfully traverse this rejection.

As discussed above in connection with the 35 U.S.C. Section 102(b) rejection, there is absolutely nothing in Petry et al. that teaches or suggests to one of ordinary skill in the art that a large polycation that is not conjugated to an enzyme can be used in a specific-binding

assay to decrease the interference caused by non-optimal serum or plasma sample preparation techniques, including, but not limited to, inadequate centrifugation, incomplete clotting time, exposure to thermal stresses, etc. As discussed above, Petry et al. actually teach away from the present invention. The only teaching that Petry et al. disclose is that the combination of an enzyme and a water-soluble protein or a non-proteinaceous natural, synthetic or semi-synthetic polymer or oligomer can be used in assays to "reduce the interaction of the unknown interferents". Petry et al. also teach that the second component of the scavenger-conjugate (the non-enzyme) is ineffective to reduce the interaction of "unknown interferents". Therefore, in view of the aforementioned arguments, Applicants submit that the rejection of claims 15 and 16 as obvious in view of Petry et al. is improper and should be withdrawn.

Claim 14 is rejected under 35 U.S.C. Section 103(a) as being unpatentable over Petry et al. in view of Massey et al. (U.S. Patent No. 5,798,083). The Examiner states that Petry fails to teach acridinium as chemiluminescent label and that Massey et al. teach a chemiluminescent TSH immunoassay comprising a monoclonal anti-TSH antibody coated magnetic microparticles. Applicants respectfully traverse this rejection.

The deficiencies of Petry et al. have been discussed in detail above in connection with the rejection of claims 1-13 under 35 U.S.C. Section 102(b) and the rejection of claims 15-16 under 35 U.S.C. Section 103(a). Applicants herein incorporate by reference their arguments made

previously. The deficiencies of Petry et al. are not cured by Massey et al. Therefore, in view of the aforementioned arguments, Applicants submit that this rejection should be withdrawn.

Claim 17 is rejected under 35 U.S.C. Section 103(a) as being unpatentable over Cantor (U.S. Patent No. 5,994,085) in view of Diamandis (U.S. Patent No. 5,688,658). The Examiner states that Cantor teaches a method for detecting free prostate specific antigen (fPSA). The method involves pretreating the sample to remove complex PSA and then assaying the fPSA by a sandwich immunoassay using two antibodies. The first antibody is specific for fPSA and is affixed on a solid phase. The second antibody is specific for another epitope site on the fPSA and contains a signal component that can be measures, such as a fluorescer, luminescent molecule, etc. The Examiner states that Cantor fails to teach using acridinium as a luminescent label. The Examiner cites Diamandis as teaching using chemiluminescent labels such as acridinium esters in an immunoassay to detect prostate specific antigen. Applicants respectfully traverse this rejection.

Claim 17 has been amended to recite that the method employs an assay diluent that comprises a large polycation. The inclusion of the large polycation is necessary in order to decrease the interferences that cause inaccurate readings in the assay. Neither Cantor nor Diamandis disclose or suggest a method that employs a large polycation in order to decrease interferences that cause inaccurate readings in a PSA assay. Therefore, in view of

this amendment to claim 17, Applicants submit that this rejection should be removed.

Claim 26 is rejected under 35 U.S.C. Section 103(a) as being unpatentable over Allard et al. (U.S. Patent No. 6,107,049) in view of Diamandis (U.S. Patent No. 5,688,658). The Examiner states that Allard teaches a two-site immunometric assay method (a sandwich method) for determining total PSA or tPSA, where two anti-PSA antibodies are employed. One of the anti-PSA antibodies is labeled (a detection antibody) and the other is immobilized (capture antibody) on a solid phase. The capture and the detection antibodies are contacted simultaneously or sequentially with the test sample. The Examiner states that Allard fails to teach using an acridinium label and cites Diamandis that teaches using acridinium esters as chemiluminescent labels in immunoassays. Applicants respectfully traverse this rejection.

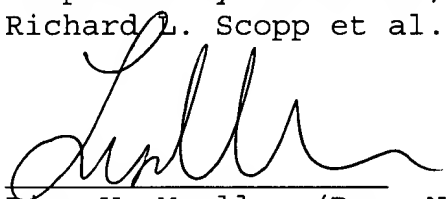
Claim 26 has been amended to recite that the method employs an assay diluent that comprises a large polycation. The inclusion of the large polycation is necessary in order to decrease the interferences that cause inaccurate readings in the assay. Neither Allard nor Diamandis disclose or suggest a method that employs a large polycation in order to decrease interferences that cause inaccurate readings in a PSA assay. Therefore, in view of this amendment to claim 26, Applicants submit that this rejection should be removed.

Action Requested

Applicant respectfully submits that present claims 1-17 and 26 are patentable over the cited art of record and urge allowance of these claims and passage to issue of the subject application. However, Applicant's attorney notes her availability for a telephone interview, and urges the Examiner to consider a telephone discussion to resolve any issues deemed outstanding by the Examiner.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account number 23-0785.

Respectfully submitted,
Richard L. Scopp et al.



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